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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/161,122	09/25/1998	HONG JIN	7682-45	7220

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PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/161,122	JIN ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-12,14-17 and 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,13,18,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Status of the Application

1. In this application, claims 1-26 are pending. Claims 2, 13, 18, 25, and 26 are pending and under consideration. Claims 1, 3-12, 14-17, and 19-24 have been withdrawn from consideration as to non-elected inventions. An action (the prior action) was mailed in the application on April 21, 2003. In the Response to this action, filed June 30, 2003, the Applicant amended the specification, and claims 2 and 18.

2. Because this action raises new grounds of rejection, it is being made Non-Final.

Priority

3. **(Prior Objection, Withdrawn)** The application, filed under former 37 CFR 1.62, was objected to as lacking the necessary reference to the prior application. In view of the Amendments of June 30, 2003, the objection is withdrawn.

Specification

4. **(Prior Objection-Withdrawn)** The specification was objected to in the prior action because it did not provide sequence identification numbers for the sequences disclosed therein. In view of the amendments to the Description of the Drawings made in the response filed September 5, 2002, this objection is withdrawn.

Claim Objections.

5. **(Prior Objection-Withdrawn)** The objection to Claim 2 is withdrawn in view of the Applicant's traversal.

Double Patenting

6. **(New Rejection)** Claims 2, 13, 18, and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 7 of U.S. Patent No. 5,840,520. Although the conflicting claims are not identical, they are not patentably distinct from each other because, while the claims of the patent do not indicate that the heterologous genes to the claimed chimeric RSV include antigenic proteins of both RSV A and B or describe the mutation of the L gene, these limitations are described by the specification with reference to the chimeric RSV. Columns 46-47. The current claims are therefore obvious variants of the patent claims.

7. **(New Rejection)** Claims 2, 13, 18, and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 7 of U.S. Patent No. 5,840,520. Although the conflicting claims are not identical, they are not patentably distinct from each other because, while the claims of the patent do not indicate that the heterologous genes to the claimed chimeric RSV include antigenic proteins of both RSV A and B or describe the mutation of the L gene, these limitations are described by the specification with

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reference to the chimeric RSV. Columns 46-47. The current claims are therefore obvious variants of the patent claims.

8. **(New Rejection)** Claims 2, 13, 18, and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25, 26, 27, and 32 of copending application 09/923,070. Although the conflicting claims are not identical, they are not patentably distinct from each other because, these claims read on overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. **(New Rejection)** Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 5,820,871, and claims 1 and 16 of U.S. Patent No. 5,166,057. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the two patents encompass the subject matter of the current application, and because in the specifications of the patents indicate that among the negative stranded RNA virus encompassed by the claims is RSV. Column 15 in the 871 patent, and column 16 in the 057 patent.

10. **(New Rejection)** Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over either claims 1 and 12 of U.S. Patent No. 5,820,871, or claims 1 and 16 of U.S. Patent No. 5,166,057, in view of U.S. Patent 6,033,668,

issued to Klein et al. The teachings of the two other patents have been described above. The patents also indicate that chimeric viruses may be used in vaccine compositions. Column 1 of the 871 patent, and column 2 of the 057 patent. Neither of these patents suggests the making of recombinant RSV encoding antigens to both the A and B strains of the virus. However, the Klein patent teaches that both strains of the RSV virus are major viral pathogens. Col 1, lines 34-37. It would therefore have been obvious to one of ordinary skill in the art to have incorporated antigens of both strains into a single virus according to the claimed patents such that a bivalent vaccine could be made against both RSV strains.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. **(Prior Rejection-Withdrawn)** Claim 18 was rejected in the prior action under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendments to the claims made in the Response, this rejection is withdrawn.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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14. **(New Rejection)** Claims 2, 13, 18, 25, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims read on chimeric RSV virus comprising a binding site for "an RNA- directed RNA polymerase. The claims therefore read on embodiments wherein the polymerase can be other than an RSV RNA directed polymerase.

However, the application does not provide any examples of such other RNA directed RNA polymerases, and indicates that the RSV polymerase is the protein envisaged by the Applicant. See, e.g. page 15, lines 11-23 (describing the RSV RNS directed polymerase, and DNA directed polymerases from other viruses), and page 20, lines 21-30 (stating "the RSV virus polymerase proteins may be expressed in any expression vector/host cell system..."). Thus, the Applicant has not provided adequate written descriptive support for the full breadth of the claimed invention.

Conclusion

15. The subject matter of claims 2, 13, 25, and 26 appears to be free of the prior art. Claim 26 is objected to as depending on a rejected claim.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

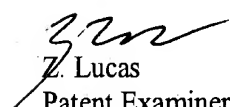
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner
July 14, 2003


JAMES HOUSEL 7/15/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600